

exception of transshipments, heels, used controlled substances, and essential use CFCs." This correction clarifies that the import restriction does not apply to CFCs produced by non-U.S. entities under the authority of privileges granted by the Parties and the national authority of another country for use in essential metered dose inhalers. *See* 67 FR 6351 (February 11, 2002).

## VII. Statutory and Executive Order Reviews

### A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this action is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

### B. Paperwork Reduction Act

This action does not add any information collection requirements or increase burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et. seq.* OMB previously approved the information collection requirements contained in the final rule promulgated on May 10, 1995, and assigned OMB control number 2060-0170 (EPA ICR No. 1432.21).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or to provide information to or for a Federal agency. This includes the time needed to review instruction; develop, acquire, install, and utilize technology

and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 1.

### C. Regulatory Flexibility Act

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impact of today's rule on small entities, the term small entities is defined as: (1) Pharmaceutical preparations manufacturing businesses (NAICS code 325412) that have less than 750 employees; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This rule provides an otherwise unavailable benefit to those companies that are receiving essential use allowances.

Although this proposed rule will not have significant economic impact on a substantial number of small entities, we continue to be interested in the potential impact of the proposed rule on small entities and welcome comments related to these issues.

### D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public

Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year.

Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative, if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed a small government agency plan under section 203 of the UMRA. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector, since it merely provides exemptions from the 1996 phase out of class I ODSs. Similarly, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments, because this rule merely allocates essential use exemptions to entities as an exemption to the ban on production and import of class I ODSs.

### E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State